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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,760	09/27/2005	Anders Ljunggren	133087.09001	3784

52286 7590 09/21/2009

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
09/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/550,760	**Applicant(s)** LJUNGGREN ET AL.	
	Examiner TIMOTHY P. THOMAS	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *5* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *11 and 17-20*.
   Claim(s) withdrawn from consideration: *14-16 and 21-25*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

Continuation of 11. does NOT place the application in condition for allowance because: The rejection of record is maintained for the reasons of record.

Applicant argues the present invention is directed to treating metabolic syndrome in a human; that the Ortlepp reference is irrelevant for the present invention, which regards humans. This is not persuasive; the limitation of "a human" is not a requirement of the instant claims, the claims recite "a subject".

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., metabolic syndrome refers to humans, according to WHO) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, the passage referenced in the specification at p. 2, lines 7-20 does not define metabolic syndrome as being limited to humans; although a reference is made in 3 a) to men or women, these are only alternative options, and are not requirements of any other criteria.

Applicant argues there is no baseline given in Ortlepp for plasma triglycerides; placebo is given at a level lower than the definition of a human diagnosed with metabolic syndrome would have; Ortlepp does not teach a threshold; that blood pressure baseline is about 110/70; that the mice participating in the study would not have fulfilled the parmeters to be diagnosed with having the metabolic syndrome, had they been humans; that the mice did not have metabolic syndrome according to the WHO definition. This is not persuasive; the clear teaching that the mice had a metabolic syndrome (abstract) is taken at face value for the teaching; additionally the mice are taught as an animal model for metabolic syndrome, which would lead to the suggestion of treating a human with metabolic syndrome, using an angiotensin II receptor antagonist. Additionally, baseline conditions are not referenced in the definition of the instant specification and are not relevant; the mice at endpoints placebo group had 1) BP 146/91 (Table 2), meeting the defined BP levels; 2) the mice are taught to have obesity (which would correlate to the required body mass index, at least in a human); since fasting plasma glucose levels and other parameters of Item 3 are not reported, the argument that a mouse model clearly taught as a metabolic syndrome somehow does not render obvious the claimed method being applied to a human with metabolic syndrome (which would characteristically meet the criteria used to diagnose the conditions) is not persuasive.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

The argument that a person skilled in the art would not draw any conclusions as to the usefulness of angiotension II inhibitors for treating metabolic syndrome because the mice do not meet the exact same criteria as set out by WHO is not persuasive. The result of significant reduction in hypertension, cardiac hypertrophy and artherosclerosis, taken with the prevention of development of obesity and hyperinsulinemia are significant results that would clearly motivate the use of an angiotensin II receptor antagonist to an individual meeting the required criteria for metabolic syndrome; one of skill in the art would have a reasonable expectation of similar outcomes when treating a human with metabolic syndrome.